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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/708,475      11/09/2000      Joseph T. Strupczewski      2489.0028-12      7075

22852      7590      12/14/2001

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/708,475

Applicant(s)

STRUPCZEWSKI et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 25-115 is/are rejected.
- 7) ☒ Claim(s) 14-24 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

Claims 1-115 are pending in the application.

Note: the preliminary amendment filed November 9, 2000 requesting that the title be changed from Piperidines to Piperazines has not been entered. Piperidines does not appear in the title but rather Heteroaryl piperidines.

#### ***Reissue Applications***

1. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:
  - a) The oath/declaration fails to state that the applicants' are the original **and first** inventors.
2. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

#### ***Specification***

3. If the reissue application is a division or a continuation of another copending reissue application, the related applications must be amended to include a cross reference to the other(s) at line 1 of the first page of the specification.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-29, 35-39, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of R where R is acyl or (C<sub>2</sub>-C<sub>11</sub>) alkanoyl is not described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 and 25-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1 (and claims dependent thereon) are missing a semicolon “:” after formula in the first line which appears in claim 1 of U.S. 5,658,911.
- b) Claims 1 (and claims dependent thereon) include parenthesis around the R<sub>1</sub> definition, i.e. (R<sub>1</sub>) on page 2 of the preliminary amendment which does not appear in claim 1 of U.S. 5,658,911.
- c) Claims 1 (and claims dependent thereon) include a comma after the variable R<sub>21</sub> in the definition of R<sub>1</sub> which does not appear in claim 1 of U.S. 5,658,911.

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- d) Claims 1 (and claims dependent thereon) include a comma after the  $-(CH_2)_n-$  in the definition of  $R_{20}$  which does not appear in claim 1 of U.S. 5,658,911.
- e) Claims 1 (and claims dependent thereon) are missing a comma after the number 4 in the definition of  $n$  which appears in claim 1 of U.S. 5,658,911.
- f) Claims 1 (and claims dependent thereon) include a hyphen “-” in the moiety  $-CH_2-CH=CH-CH_2-CH_2-$  in line 5 of page 3 which does not appear in claim 1 of U.S. 5,658,911.
- g) Claims 1 (and claims dependent thereon) include a hyphen “-” in the moiety  $-CH_2-CH_2-C\equiv C-CH_2-$  in line 8 of page 3 which does not appear in claim 1 of U.S. 5,658,911.
- h) Claims 1 (and claims dependent thereon) are missing a comma after the moiety “phenyl group” in the definition of  $R_{22}$  which appears in claim 1 of U.S. 5,658,911.
- i) Claims 1 (and claims dependent thereon) include the moiety “lower” alkoxy in the definition of  $R_9$  on page 4 which does not appear in claim 1 of U.S. 5,658,911.
- j) Claims 1 (and claims dependent thereon) are missing a comma after “optical” in eighth line on page 5 which appears in column 106 of claim 1 in U.S. 5,658,911.
- k) Claim 9 recites the limitation “acyl” in the definition of  $R$ . There is insufficient antecedent basis for this limitation in the claim.

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- l) Claims 25-27 (and claims dependent thereon) recite the limitation "C<sub>1</sub>-C<sub>4</sub> alkyl, cyano, C<sub>1</sub>-C<sub>4</sub> alkoxy and -COOR<sub>23</sub> where R<sub>23</sub> is C<sub>1</sub>-C<sub>4</sub> alkyl" in the first proviso. There is insufficient antecedent basis for this limitation in the claim.
- m) Claims 26-29 (and claims dependent thereon) includes a semicolon after the moiety "-CH(OR<sub>7</sub>)-alkyl" in the definition of R where a comma appears in claims 26-29 of U.S. 5,658,911.
- n) Claims 30-33 (and claims dependent thereon) include an "as" in the fifth line on page 12 which do not appear after where aryl is, in line 21 of column 110 of U.S. 5,658,911. See also "where aryl is defined hereinafter" in claims 31-33
- o) Claims 30-33 (and claims dependent thereon) include parenthesis around the R<sub>1</sub> definition, i.e. (R<sub>1</sub>) on pages 2, 16, of the preliminary amendment which do not appear in claims 30-33 of U.S. 5,658,911.
- p) Claims 30-33 (and claims dependent thereon) include a comma after the variable R<sub>21</sub> in the definition of R<sub>1</sub> which do not appear in claims 30-33 of U.S. 5,658,911.
- q) Claims 30-33 (and claims dependent thereon) include a comma after the -(CH<sub>2</sub>)<sub>n</sub>- in the definition of R<sub>20</sub> which do not appear in claims 30-33 of U.S. 5,658,911.
- r) Claims 30-33 (and claims dependent thereon) are missing a comma after the number 4 in the definition of n which appears in claims 30-33 of U.S. 5,658,911.

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- s) Claims 30-33 (and claims dependent thereon) include a hyphen “-” in the moiety -  $\text{CH}_2\text{-C}\equiv\text{C-CH}_2\text{-CH}_2\text{-}$  in line 15 of page 12, line 7 of page 16, etc. which do not appear in claims 30-33 of U.S. 5,658,911.
- t) Claims 30-33 (and claims dependent thereon) include a hyphen “-” in the moiety -  $\text{CH}_2\text{-CH}_2\text{-C}\equiv\text{C-CH}_2\text{-}$  in line 18 of page 12, line 10 of page 16, etc. which do not appear in claims 30-33 of U.S. 5,658,911.
- u) Claims 30 (and claims dependent thereon) include a capital letter in the definition of  $\text{R}_{22}$ , i.e. iS.
- v) Claims 30-33 (and claims dependent thereon) include the term “one” in the definition of the substituents for  $\text{R}_{20}$  or  $\text{R}_{21}$ , however the definition of the substituents for  $\text{R}_{20}$  or  $\text{R}_{21}$  in claims 30-33 of U.S. 5,658,911 is “on”, i.e. the e is missing.
- w) Claims 30-33 (and claims dependent thereon) are missing a comma after the moiety “phenyl group” in the definition of  $\text{R}_{22}$  which appears in claims 30-33 of U.S. 5,658,911.
- x) Claims 30 and 31 (and claims dependent thereon) include an “e” in the moiety “lower alkyleneyl” which is bonded to the phenyl ring substituent in the definition of  $\text{R}_{22}$  on pages 13 and 16 which do not appear in claims 30 and 31 of U.S. 5,658,911.

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- y) Claims 30-33 (and claims dependent thereon) include the moiety “lower” alkoxy in the definition of  $R_9$  on pages 14, 17, etc. which do not appear in claims 30-33 of U.S. 5,658,911.
- z) Claims 30-33 (and claims dependent thereon) are missing a comma after “optical” in the eighth line on page 14, the ninth line of page 18, etc. which appears in claims 30-33 in U.S. 5,658,911.
- aa) Claims 30 (and claims dependent thereon) are missing a “, and a pharmaceutically acceptable carrier therefor” in the last line on page 14 which appears in claim 30 of U.S. 5,658,911.
- bb) Claims 31-32 (and claims dependent thereon) are missing an open parenthesis before the moiety  $C_3-C_{10}$ cycloalkyl in the definition of  $R_2$  which appears in claims 31-32 of U.S. 5,658,911.
- cc) Claim 31 is vague and indefinite in that it is not known what is meant by “a p” in the definition of  $Z_1$ .
- dd) Claims 46, 66, 86-89, 92 and 93 (and claims dependent thereon) are missing the “as” in the phrase “aryl is defined hereinafter” that appears in claim 1. The applicants are invited to amend this phrase to correspond to the other claims.
- ee) Claim 49 recites the limitation “n is 2, 3, or 4” in the claim. There is insufficient antecedent basis for this limitation in the claim.



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- ff) Claim 54 recites the limitation "acyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claim.
- gg) Claim 54 recites the limitation "n is 2, 3, or 4" in the claim. There is insufficient antecedent basis for this limitation in the claim.
- hh) Claim 57 recites the limitation "3" in the definition of n. There is insufficient antecedent basis for this limitation in the claim..
- ii) Claim 74 recites the limitation "acyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claim.
- jj) Claims 96 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the "or" which appears before the moiety -CH(OR<sub>7</sub>)-alkyl indicating the end of the definition which is not so.
- kk) Claims 96 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the semicolon ";" which appears after the moiety -CH(OR<sub>7</sub>)-alkyl indicating the end of the definition which is not so.
- ll) Claim 104 recites the limitation "acyl" in the definition of R. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25-29, 35-39, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Strupczewski et al., EP 402 644. EP 402 644 teaches the compounds, compositions and method of use of the compounds of the instant invention where X is O, S, NH or N(R<sub>2</sub>), n is 2, 3 or 4, R is hydrogen, hydroxyl, -C(=O)-n-butyl, -NHMe, -C(=O)-Et, ethoxy, -CH(OAc)-Me, -C(=O)-CF<sub>3</sub>, methyl, -NHAc, bromine, methoxy, acetyl, -CH(OAc)-Me, -CH(OEt)-Me and/or -CH(OH)-Me and Y is hydrogen, F or Cl. It is recognized benefit under 35 USC 120 is being urged. However, claims 25-29, 35-39, 44 and 45 of instant application are only entitled to benefit of November 9, 2000 as it is only completely described in the instant application. Note *In re Scheiber* 199 USPQ 782 regarding 112 compliance for benefit under 35 USC 120.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6, 10-13, 30, 35, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strokbroekx et al., EP 0 398 425. The generic structure of EP '425 encompasses the instantly claimed compounds (see Formula I, page 3). Examples 50-55, etc.

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differ only in the nature of the R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> substituents. Page 3, lines 45-48 defines the substituent R<sup>1</sup> and R<sup>2</sup> as hydrogen, C<sub>1-4</sub> alkyl or halo and R<sup>3</sup> as hydrogen, halo, cyano, C<sub>1-4</sub> alkyloxy, aryl or -COOR<sup>4</sup>, with R<sup>4</sup> being hydrogen, C<sub>1-4</sub> alkyl, arylC<sub>1-4</sub> alkyl, C<sub>3-6</sub>cycloalkylC<sub>1-4</sub> alkyl, C<sub>3-5</sub> alkenyl, C<sub>3-5</sub> alkynyl, or C<sub>1-4</sub> alkyloxyC<sub>1-4</sub> alkyl. Compounds of the instant invention are generically embraced by EP '425 in view of the interchange ability of R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> substituents of the phenyl ring. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example instant R is carboxyl and X is NH as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

8. Claims 1-4, 6, 9-13, 25, 27, 30, 33-35, 38-39 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., U.S. Patent No. 4,590,196. The generic structure of U.S. '196 encompasses the instantly claimed compounds (see Formula I, column 3) and for the same uses as claimed herein. Examples 55 and 56 differ only in the nature of the R<sup>3</sup> and R<sup>4</sup> substituent. Column 3, lines 20-23 defines the substituent R<sup>3</sup> and R<sup>4</sup> as hydrogen, lower alkyl, lower acyloxy, lower alkoxy, lower alkylthio, halogen, or hydroxyl or trifluoromethyl. Compounds of the instant invention are generically embraced by U.S. '196 in view of the interchange ability of R<sup>3</sup> and R<sup>4</sup> substituents of the bicyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example amino CF<sub>3</sub> as well as other possibilities from the generically disclosed alternatives of the

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reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.


***Claim Objections***

9. Claims 14-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
Brenda Coleman  
Primary Examiner AU 1624  
December 13, 2001